

EXHIBIT 1

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

MEDICIS PHARMACEUTICAL
CORPORATION,

Plaintiff,

v.

NYCOMED US INC. and NYCOMED
GMBH

Defendants.

Civil. Action No. 10-CV-4140-LAK

**NYCOMED US INC.'S AMENDED ANSWER,
AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendant Nycomed US Inc. (“Nycomed US”) through its undersigned counsel, responds to the allegations in the Complaint of Plaintiff Medicis Pharmaceutical Corporation (“Medicis”) as follows:

PARTIES

1. Nycomed US is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 1 of the Complaint, which are therefore denied.
2. Nycomed US admits the allegations of paragraph 2 of the Complaint.
3. The allegations in this paragraph concern Nycomed GmbH and are not directed toward Nycomed US, and therefore do not require a response from Nycomed US.
4. Denied.
5. Nycomed US is unable to determine what Medicis means by the term “conducts operations,” and therefore denies the allegations contained in Paragraph 5 of the Complaint. As

to the allegations in this paragraph that concern Nycomed GmbH, these allegations are not directed toward Nycomed US, and therefore do not require a response from Nycomed US.

6. Denied.

JURISDICTION AND VENUE

7. For its response to Paragraph 7 of the Complaint, Nycomed US admits that Medicis contends that it has brought a patent infringement action against Nycomed US under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, but Nycomed US denies that Medicis had a legal or equitable basis to do so and otherwise denies the allegations in this paragraph. Nycomed US expressly denies any infringement and that Medicis is entitled to any relief.

8. Paragraph 8 of the Complaint contains legal conclusions to which no answer is required.

9. Paragraph 9 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Nycomed US does not contest venue for purposes of this action only. Nycomed US denies the remaining allegations of this paragraph.

10. Paragraph 10 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Nycomed US does not contest personal jurisdiction for purposes of this action only. As to the allegations in this paragraph that concern Nycomed GmbH, these allegations do not require a response from Nycomed US.

BACKGROUND

11. Nycomed US admits that U.S. Patent No. 6,765,001 (the ‘001 patent”) is entitled “Compositions And Methods For Enhancing Corticosteroid Delivery,” and that on the face of the patent the date of issuance is listed as July 20, 2004, and “Medicis Pharmaceutical Corporation”

is named as the Assignee. Nycomed US also admits that Exhibit A purports to be a copy of the '001 patent. Nycomed US denies that the '001 patent was duly or legally issued. Nycomed US is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 11, which are therefore denied.

12. Nycomed US admits that U.S. Patent No. 7,220,424 (the ‘424 patent’) is entitled “Compositions And Methods For Enhancing Corticosteroid Delivery,” and that on the face of the patent the date of issuance is listed as May 22, 2007, and “Medicis Pharmaceutical Corporation” is named as the Assignee. Nycomed US also admits that Exhibit B purports to be a copy of the ‘424 patent. Nycomed US denies that the ‘424 patent was duly or legally issued. Nycomed US is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 12, which are therefore denied.

13. Nycomed US admits that U.S. Patent No. 7,217,422 (the ‘422 patent”) is entitled “Compositions And Methods For Enhancing Corticosteroid Delivery,” and that on the face of the patent the date of issuance is listed as May 15, 2007, and “Medicis Pharmaceutical Corporation” is named as the Assignee. Nycomed US also admits that Exhibit C purports to be a copy of the ‘422 patent. Nycomed US denies that the ‘422 patent was duly or legally issued. Nycomed US is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 13, which are therefore denied.

14. Nycomed US is without knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 14 of the Complaint. Nycomed US admits the allegations contained in the second sentence of Paragraph 14 of the Complaint.

15. Nycomed US is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 15 of the Complaint, which are therefore denied.

16. Nycomed US admits that it submitted Abbreviated New Drug Application No. 200735 pursuant to 21 U.S.C. § 355(j) to obtain approval to market its Fluocinonide Cream, 0.1% before the expiration dates of the '001 and '424 patents. Nycomed US further admits that pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Nycomed US also filed with the FDA a Paragraph IV Certification stating that, in its opinion, and to the best of its knowledge, all of the claims of the '001 and '424 patents will not be infringed by the manufacture, use, sale, offer for sale, importation or offer to import the product. Nycomed US denies the remaining allegations of this paragraph.

17. Nycomed US is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 17 of the Complaint, and therefore denies the same.

COUNT I
INFRINGEMENT OF THE ‘001 PATENT

18. Nycomed US hereby incorporates, as though fully set forth herein, its responses above to Paragraphs 1 through 17 of the Complaint, in answer to the allegations contained in Paragraph 18 of the Consolidated Complaint.

19. Paragraph 19 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Nycomed US denies the allegations contained in Paragraph 19 of the Complaint.

20. Nycomed US admits that it intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States, of its fluocinonide cream, 0.1%, at an undetermined time after final approval of its ANDA. Nycomed US denies the remaining allegations of this paragraph.

21. Denied.

22. Denied.

23. Denied.

COUNT II
INFRINGEMENT OF THE '424 PATENT

24. Nycomed US hereby incorporates, as though fully set forth herein, its responses above to Paragraphs 1 through 23 of the Complaint, in answer to the allegations contained in Paragraph 24 of the Consolidated Complaint.

25. Paragraph 25 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Nycomed US denies the allegations contained in Paragraph 25 of the Complaint.

26. Nycomed US admits that it intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States, of its fluocinonide cream, 0.1%, at an undetermined time after final approval of its ANDA. Nycomed US denies the remaining allegations of this paragraph.

27. Denied.

28. Denied.

29. Denied.

COUNT III
INFRINGEMENT OF THE '422 PATENT

30. Nycomed US hereby incorporates, as though fully set forth herein, its responses above to Paragraphs 1 through 29 of the Complaint, in answer to the allegations contained in Paragraph 30 of the Consolidated Complaint.

THIRD AFFIRMATIVE DEFENSE

3. Medicis is barred by proper claim construction and/or estoppel from asserting infringement of the patents in this suit.

FOURTH AFFIRMATIVE DEFENSE

4. The claims of the patents in this suit are invalid and/or void for failure to comply with one or more requirements of Part II of Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and 112.

FIFTH AFFIRMATIVE DEFENSE

5. The Court lacks subject matter jurisdiction over Medicis’ claims for patent infringement against Nycomed US.

SIXTH AFFIRMATIVE DEFENSE

6. Medicis' claims fail to state a claim upon which relief can be granted.

SEVENTH AFFIRMATIVE DEFENSE

7. Medicis' claims should be dismissed for the reasons set forth in Nycomed US' Motion to Dismiss Pursuant to Rules 12(b)(1) and 12(b)(6).

EIGHTH AFFIRMATIVE DEFENSE

8. Medicis is not entitled to injunctive relief because any alleged injury to Medicis is not immediate or irreparable, and Medicis has an adequate remedy at law.

NINTH AFFIRMATIVE DEFENSE

9. Any additional defenses or counterclaims that discovery may reveal.

NYCOMED US'S COUNTERCLAIMS

Counterclaimant Nycomed US Inc. (“Nycomed US”) hereby brings its counterclaims against counterclaim-defendant Medicis Pharmaceutical Corporation (“Medicis”) as follows:

PARTIES

1. Counterclaimant Nycomed US is a company organized and existing under the laws of the State of New York, having a place of business at 60 Baylis Road, Melville, New York 11747.

2. On information and belief, and based upon its pleadings in this action, counterclaim-defendant Medicis is a corporation organized and existing under the laws of the State of Delaware having a place of business at 7720 North Dobson Road, Scottsdale, Arizona 85256.

JURISDICTION AND VENUE

3. This Court has jurisdiction over this counterclaim pursuant to 28 U.S.C. §§ 1331, 1338, 2201 and 2202.

4. By filing its Complaint, Medicis has consented to the personal jurisdiction of this Court. In addition, personal jurisdiction over Medicis is proper in this district because Medicis has availed itself of the rights and privileges of this forum by suing in this district and because, on information and belief, Medicis conducts substantial business in, and has regular systematic contact with, this district.

5. Venue for this action is proper pursuant to 28 U.S.C. §§ 1391. In addition, venue for these counterclaims is proper in this district because Medicis has consented to venue in this Court by filing the instant action in this jurisdiction.

FACTS

6. Upon information and belief, Medicis claims to be the owner of all rights, title, and interest in and to the '001 and '424 patents.

7. In its Complaint, Medicis has accused Nycomed US of infringing the ‘001 and ‘424 patents under 35 U.S.C. § 271(e)(2)(A) through Nycomed’s submission of Abbreviated New Drug Application No. 200735 to obtain approval to market its Fluocinonide Cream, 0.1%. Nycomed US denies that its Fluocinonide Cream, 0.1%, infringes the ‘001 and ‘424 patents and further believes that the ‘001 and ‘424 patents are invalid.

8. Because Medicis has accused Nycomed US of infringement under 35 U.S.C. § 271(e)(2)(A), an actual case and controversy exists between the parties concerning the infringement and validity of the '001 and '424 patents, and that controversy is ripe for adjudication by this Court.¹

FIRST COUNTERCLAIM

(Declaration of Non-Infringement of the '001 and '424 Patents)

9. Nycomed US repeats and realleges the allegations contained in paragraphs 1-8 of Nycomed US's Counterclaims as if fully set forth herein.

10. Nycomed US did not infringe any valid claim of the ‘001 or ‘424 patents by submitting ANDA No. 200735.

11. The manufacture, use, offer for sale, sale, or importation of the fluocinonide cream, 0.1% product described in Nycomed US' ANDA will not infringe any valid claim of the '001 or '424 patents.

¹ Nycomed US has filed a motion to dismiss the claims relating to the '422 patent based upon lack of subject matter jurisdiction and failure to state a claim on which relief can be granted. In the event that Nycomed US' motion is denied, Nycomed US reserves its right to amend its answer to include counterclaims pertaining to the '422 patent.

SECOND COUNTERCLAIM

(Declaration of Invalidity of the '001 and '424 Patents)

12. Nycomed US repeats and realleges the allegations contained in paragraphs 1-11 of Nycomed US's Counterclaims as if fully set forth herein.

13. Each and every claim of the ‘001 and ‘424 patents is invalid for failing to meet one or more of the requisite conditions for patentability specified by Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and 112.

PRAYER FOR RELIEF

WHEREFORE, Nycomed US requests that the Court enter a judgment in its favor and against Medicis as follows:

- a. Dismiss Medicis's Complaint in its entirety, with prejudice;
- b. Enter judgment in favor of Nycomed US and against Medicis;
- c. Declaring that the filing of Nycomed's ANDA No. 200735 does not infringe any valid claims of the '001 and '424 patents;
- d. Declaring that the manufacture, use, sale, offer for sale, importation or offer to import the fluocinonide cream, 0.1% product described in Nycomed US' ANDA does not infringe (either literally or under the doctrine of equivalents), directly or indirectly, any valid claim of the '001 and '424 patents;
- e. Declare that the '001 and '424 patents are invalid;
- f. Award Nycomed US its costs (including expert fees), disbursements, and reasonable attorneys' fees incurred in this action, pursuant to 35 U.S.C. § 285; and

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g. Grant such other and further relief as the Court may deem just and proper.

Respectfully Submitted,

DATED: December 23, 2010

/s/ David B. Bassett
David B. Bassett
david.bassett@wilmerhale.com
David A. Manspeizer
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WILMER CUTLER PICKERING HALE
AND DORR LLP
399 Park Avenue
New York, New York 10022
(212) 230-8800 (tel.)
(212) 230-8888 (fax)

Attorneys for Defendant Nycomed U.S. Inc.

EXHIBIT 2

James Baker

From: James Baker
Sent: Tuesday, May 04, 2010 7:15 PM
To: 'drhoads@kramerlevin.com'
Cc: Andrew Berdon
Subject: Nycomed Offer of Confidential Access
Attachments: OCA.pdf

Don,

Thank you for your voice message. Attached please find Medicis' proposed changes to Nycomed's Offer of Confidential Access.

Best regards,
Jim

James Baker
Associate,
Quinn Emanuel Urquhart & Sullivan, LLP

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**OFFER OF CONFIDENTIAL ACCESS TO NYCOMED US INC.'S
ABBREVIATED NEW DRUG APPLICATION
ANDA No. 200735**

Pursuant to §505(j)(5)(C)(i)(III) of the Federal Food, Drug, and Cosmetic Act (“the Act”)², this letter includes an Offer of Confidential Access to Application (“Offer”). Nycomed US Inc. (“Nycomed”) hereby offers to provide confidential access to certain information from its ANDA No. 200735 for the sole and limited purpose of determining whether a patent infringement action referred to in §505(j)(5)(B)(iii) of the Act should be brought. Pursuant to §505(j)(5)(C)(i) of the Act, by providing this Offer, Nycomed maintains the right and ability to bring a declaratory judgment action under 28 U.S.C. §§ 2201 *et seq.*

² 21 U.S.C. § 355(j)(5)(C)(i)(III). This provision titled “ Offer of confidential access to application” states:

For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

Section 505(j)(5)(C)(i)(III) of the Act allows Nycomed to impose “restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information.” Under the same provision of the Act, Nycomed has the right to and will redact its ANDA to remove any information that is irrelevant to any issue of patent infringement in response to a request for access under this Offer.

Terms and Restrictions of Offer

A. Nycomed will permit access to certain information from its proprietary ANDA (“Nycomed’s Confidential Information”). Access to Nycomed’s Confidential Information shall be limited solely to:

(1) outside counsel attorneys from one outside law firm appointed by and representing Medicis Pharmaceutical Corporation (“Medicis”), and any employees and assistants under the control of such outside counsel; ~~provided, however, that such attorneys do not engage, formally or informally, in any patent prosecution, FDA counseling or litigation or other work before or involving FDA, on behalf of Medicis.~~

(2) two in-house attorneys of Medicis, including patent counsel;

(3) consultants and experts who are not currently employees, officers, or directors of any party, and any employees and assistants under the control of such consultants and experts; and

~~A.~~ (4) any outside copying service.

For the purposes of access, Nycomed’s Confidential Information provided pursuant to the acceptance of this Offer will be marked “CONFIDENTIAL — OUTSIDE ATTORNEY’S EYES ONLY” and will remain proprietary to Nycomed.

B. Nycomed retains the right and will redact its ANDA to remove any information of no relevance to any issue of patent infringement in response to a request for access under this Offer.

Nycomed’s provision of access to Nycomed’s Confidential Information is in no way an admission on the part of Nycomed that such information is relevant or material to the disposition of any issue related to infringement, validity, or enforceability of U.S. Patent Nos. 6,765,001 and 7,220,424.

C. Persons receiving access to Nycomed Confidential Information shall use such information ~~The attorneys appointed by Medicis may make use of Nycomed’s Confidential Information~~ for the sole and limited purpose of determining whether an infringement action should be brought, and for no other purpose.

D. Persons receiving access to Nycomed Confidential Information shall not disclose such information ~~The attorneys appointed by Medicis shall not disclose any Nycomed Confidential Information~~ to any other person or entity, ~~including employees of the client it~~

~~represents in this matter, its or its client's outside scientific consultants, and/or other outside counsel~~ without the prior written consent of Nycomed's General Counsel or the General Counsel's designee, except that Medicis' in-house counsel shall be allowed to make disclosures of Nycomed Confidential Information to the members of Medicis' Board of Directors involved in the decision of whether an infringement action should be brought.

E. Should Medicis opt to file an infringement action against Nycomed, no information contained in or derived from Nycomed's Confidential Information may be included in any publicly available or accessible complaint or pleading, or paper filed with the court. This provision is not intended to cover, and, to the contrary, specifically excludes, any information contained in or derived from Nycomed's Notice of Certification dated April 7, 2010 from Robert J. Anderson, General Counsel & Vice President, Regulatory Affairs, Nycomed US Inc., to Jonah Shacknai, Chairman and Chief Executive Officer, Medicis Pharmaceutical Corporation.

F. In accepting this offer, Medicis agrees that its appointed outside attorneys shall Persons receiving access to Nycomed Confidential Information agree to take all measures reasonable and necessary to prevent unauthorized disclosure or use of Nycomed's Confidential Information, and that all Nycomed's Confidential Information will be kept confidential and not disclosed or used in any manner inconsistent with the terms of this Offer.

G. Before the earlier of (a) the commencement of an infringement action resulting from the filing of Nycomed's ANDA, or (b) the end of a 35-day period from first receiving Nycomed's Confidential Information, ~~the attorneys appointed by Medicis~~ all persons receiving access to Nycomed Confidential Information shall destroy ~~return to Nycomed~~ any Nycomed Confidential Information, and any copies thereof.

H. Prior to receiving access to Nycomed's Confidential Information, any person receiving such access ~~attorneys appointed by Medicis~~ shall acknowledge in writing his or her agreement to be bound by the obligations and restrictions imposed by this Offer. Such written acknowledgment shall be provided to Nycomed and Kramer Levin Naftalis & Frankel LLP at the addresses below.

I. A request for access under this Offer shall be considered acceptance of the terms and restrictions set forth herein, and the terms and restrictions shall be considered terms of an enforceable contract. The laws of the State of New York shall govern the terms and restrictions of this Offer, and any dispute arising from the Offer or its acceptance.

By accepting the terms of this Offer, Medicis further: (i) agrees that any litigation arising from this Offer or its acceptance³ shall be venued exclusively in the State of New York; (ii) consent(s) to submit to the jurisdiction of the federal courts of the State of New York; and (iii) expressly waives any objection as to jurisdiction or venue in federal courts located in the State of New York.

³ Litigation arising from this Offer or its acceptance is distinguishable from patent litigation arising from the filing of Nycomed's ANDA, for which venue and jurisdiction would be governed by statute and common-law principles.

A request for access under this Offer may be made in writing to:

Robert J. Anderson, Esq.
General Counsel
Vice President, Regulatory Affairs
Nycomed US Inc.
60 Baylis Road
P.O. Box 2006
Melville, NY 11747

Any request, correspondence, or other activity under the terms of this Offer should be directed to the person and address specified above.

With a copy to:

Donald L. Rhoads, Esq.
Kramer Levin Naftalis & Frankel LLP
1177 Avenue of the Americas
New York, NY 10036

Any request, correspondence, or other activity under the terms of this Offer involving Kramer Levin Naftalis & Frankel LLP should be directed to the person and address specified above.

James Baker

From: Rhoads, Donald L. [DRhoads@KRAMERLEVIN.com]
Sent: Tuesday, May 11, 2010 2:00 PM
To: James Baker
Subject: FW: Nycomed Offer of Confidential Access
Attachments: OCA.pdf

James:

We have looked at your changes to Nycomed's OCA and would like to discuss them with you. We are available to discuss them by telephone tomorrow (I'm out of the office today). Generally, access is granted to too many people and with too few conditions than appears to be justified. There is also no provision for checking for conflicts and the prosecution and FDA bar, which are the norm in these situations, has been removed.

Regards,
Don

Donald L. Rhoads

Partner
Kramer Levin Naftalis & Frankel LLP
1177 Avenue of the Americas
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From: James Baker [<mailto:JamesBaker@QuinnEmanuel.com>]
Sent: Tuesday, May 04, 2010 7:15 PM
To: Rhoads, Donald L.
Cc: Andrew Berdon
Subject: Nycomed Offer of Confidential Access

Don,

Thank you for your voice message. Attached please find Medicis' proposed changes to Nycomed's Offer of Confidential Access.

Best regards,

Jim

James Baker
Associate,
Quinn Emanuel Urquhart & Sullivan, LLP

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WRITER'S DIRECT DIAL NO.
(212) 849-7114

WRITER'S INTERNET ADDRESS
jamesbaker@quinnemanuel.com

May 13, 2010

VIA E-MAIL

Donald L. Rhoads
Kramer Levin Naftalis & Frankel LLP
1177 Avenue of the Americas
New York, New York 10036

Re: Nycomed Offer of Confidential Access, ANDA No. 20-735

Dear Don:

We are in receipt of your May 11, 2010 e-mail concerning Medicis' proposed changes to Nycomed's Offer of Confidential Access ("OCA"). We are writing to address, in particular, Nycomed's objection to Medicis' removal of the prosecution and FDA bars from the OCA. These provisions were removed and remain unacceptable to Medicis because they will prohibit disclosure of the Nycomed ANDA to the two in-house attorneys with ultimate responsibility for this matter – Jason Hansen, Executive Vice President and General Counsel, and Len Smith, Principal Intellectual Property Counsel. Both of these individuals will have responsibility for assessing the Nycomed ANDA and advising the Medicis Board on whether to bring an action for patent infringement. Both, however, also have direct and indirect responsibility for patent prosecution and FDA matters related to Vanos®. Thus, as a practical matter, Medicis cannot agree to the prosecution and FDA bars proposed by Nycomed. Please let us know if Nycomed will reconsider its objection or if you wish to discuss this matter further.

Sincerely,



James E. Baker

quinn emanuel urquhart & sullivan, llp

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